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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,164	04/23/2001	Vladimir Kozlov	1331-338	6786

7590

09/19/2002

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EXAMINER

CARLSON, KAREN C

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 09/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/839,164

Applicant(s)

KOZLOV ET AL.

Examiner

Karen Cochrane Carlson, Ph.D.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 0, 7A,B.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Claims 1-26 have been canceled. Claims 27-32 are currently pending and are under examination.

Claim 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 30-32 are indefinite because it is not clear what present in the milligram amounts means, as a composition comprises a concentration of a particular item, such as grams/liter, for example.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 27-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Tame et al. (1991; J. Mol. Biol. 218:761-767). Tame et al. teach  $\alpha$ -globin in a buffer solution, which is a pharmaceutically acceptable carrier (page 763, col. 1, para. 1). This  $\alpha$ -globin was diluted to 5 mg/ml with the buffer and then diluted further to 0.25 mg/ml with a potassium buffer (Claim 27).  $\beta$ -globin was added to the  $\alpha$ -globin solution in the presence of hemin dicyanide (Claim 29). Claim 28 is included in this rejection because the  $\beta$ -globin ~~-globin~~ added to the  $\alpha$ -globin solution was most likely in the same buffer as the  $\alpha$ -globin because it was added in "molar excess",

indicating that the  $\beta$ -globin was in solution and in at least the concentration of the  $\alpha$ -globin. Claims 30 to 32 are included in this rejection because there is no concentration provided in the claims, and enough of the solutions taught in Tame et al. can be made to comprise 0.1 mg to 6 g of globin.

Claim 29 and 32 is rejected under 35 U.S.C. 102(e) as being anticipated by Estep (USP 4,861,867). Estep teaches hemoglobin in phosphate buffer solution (1 g/dl) in Col. 14, Example 5. Therefore, compositions comprising  $\alpha$ - and  $\beta$ -globin is anticipated by Estep. Claim 32 is included in this rejection because there is no concentration provided in the claims, and enough of the solutions taught in Estep can be made to comprise 0.1 mg to 6 g of globin.

Claims 27-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Hoffman et al. (USP 5,449,759). Hoffman et al. teach  $\alpha$ -globin diluted to 0.3 mg/ml potassium phosphate buffer, which is a pharmaceutically acceptable carrier (col. 18, line 28; Claim 27).  $\beta$ -globin, dissolved in a tris buffer solution at 5 mg/ml (col. 18, line 25; Claim 29), was added to this  $\alpha$ -globin (col. 18, line 36; Claim 29). This solution of hemoglobin was purified and placed in a sodium phosphate buffer solution (col. 18, line 59). Additionally, col. 22, Example 3 teaches 60 g/l of hemoglobin, which is comprised of  $\alpha$ - and  $\alpha$ -globin in a physiologically acceptable blood substitute solution. Claims 30 to 32 are included in this rejection because there is no concentration provided in the claims, and enough of the solutions taught in Tame et al. can be made to comprise 0.1 mg to 6 g of globin.

No Claims are allowed.

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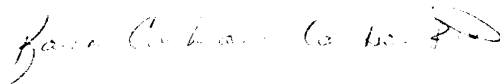
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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September 17, 2002



KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER